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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,530	05/09/2001	Kurt Klimpel	15280-290110	7146

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TOWNSEND AND TOWNSEND AND CREW
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/853,530

Applicant(s)
Klimpel et al.

Examiner
Ron Schwadron

Art Unit
1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

1. Claims 1-7 are under consideration. Claims 8-28 have been canceled.
2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows.

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

The instant application was filed as a divisional of 08/937276. Applicants need to amend the specification, page 1, to indicate that the instant application is a divisional of US application 08/937276 filed 9/15/97.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed invention which uses an APABP construct which contains amino acids 1-254 of LF is not enabling for the claimed invention which uses intact LF. The art (Arora et al., JBC, 1994) recognizes that intact LF causes cell death when administered to cells. Thus, the claimed invention which uses intact LF could not be used to induce an immune response to CTL epitopes because it would kill the treated cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

5. Claims 1-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "anthrax protective antigen binding protein". The specification page 7, lines 1 and 2, defines said term as "contains the PA binding site

of LF". The specification page 7, lines 21-23 defines LF as a 90 kDa protein derived from B. anthracis. Said protein is known in the art. The indefinite issue arises in that page 7, lines 23-24 recites "The description of LF includes binary toxin functional equivalents such as protein Ia of C. perfringens.". It is unclear from this sentence whether LF is limited to the 90 kDa protein derived from B. anthracis or whether LF encompasses includes binary toxin functional equivalents because it is unclear whether "The description of LF includes" refers to the definition of LF or has some other meaning. If the term is taken as encompassing "binary toxin functional equivalents", then it is unclear what this term means or encompasses because it is not defined in the specification and it has no art recognized meaning. It is unclear as to what properties or set of properties would be encompassed by a "binary toxin functional equivalent".

6. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . . claimed subject matter", *Vas-Cath, Inc. V. Mahurkar*, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed inventions.

As per paragraph 5 of the instant Office Action, the instant claims encompass use of a "binary toxin functional equivalents". With the exception of the particular LF derived fragment derived from the first 254 amino acids of the 90 kDa protein of B. anthracis disclosed in the specification, the skilled artisan cannot envision the detailed structure of the encompassed "binary toxin functional equivalents" and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. For example, it is clear that the peptide recited in the claims encompasses a vast number of potential analogs with varying amino acid sequences, yet there is no disclosure in the specification of what amino acid sequence would be used

other than the specific example disclosed in the specification. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. In the instant application, the amino acid itself or isolated protein is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", *Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd.*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein is stated: "The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotide that make up the cDNA." See *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leppla et al. (WO 94/18332).

Leppla et al. teach anthrax protective antigen (see last paragraph page 25 and first paragraph, page 26) and a fusion protein containing the PA binding domain of LF/growth factor, wherein growth factors are full length proteins(see last paragraph page 25 and second paragraph, page 26). Leppla et al. teach that the fusion protein can contain the first 1-254 amino acids of LF (e.g. PA binding domain)(see pages 6 and 7). The name anthrax as used by Leppla et al. refers to *Bacillus anthracis* (see last paragraph page 3, continued on next page). Processed protective antigen is created when the anthrax protective antigen is administered in vivo. Leppla et al. teach that the LF/fusion protein and PA are administered as a pharmaceutical composition (see page 27) containing saline (aqueous solution of physiologically compatible salts, see page 28). Leppla et al. do not teach the molar ratio recited in claim 1. Leppla et al. teach that the amount of PA and LF/fusion protein will be optimized using routine procedures. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Leppla teach the claimed invention except for the molar ratio recited in claim 1 and Leppla et al. teach that the amount of PA and LF/fusion

protein will be optimized using routine procedures. The recitation of an intended use in this product claim carries no patentable weight because the claimed product is the same as the product rendered obvious in the instant rejection.

9. No claim is allowed

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1600 1660

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644